

THE FLORIDA BOARD OF PHARMACY

ANNUAL REGULATORY PLAN 2019-2020

This Annual Regulatory Plan is being filed and published pursuant to section 120.74, *Florida Statutes* (2019). The Plan covers the period beginning October 1, 2019 and ending September 30, 2020.

PART ONE LAWS ENACTED OR AMENDED

Part One of the Plan addresses each law enacted or amended during the 2019 Legislative Session which creates or modifies the duties or authority of the Board of Pharmacy. §120.74(1)(a), Fla. Stat. (2019).

Law Enacted or Modified on or after Oct. 1, 2018	Florida Statute (modified or created)	Rule (impacted)	Must Agency Adopt Rules?	If Rulemaking Necessary, Notice of Development Published in Florida Administrative Register?	Expected Publication Date for Notice of Proposed Rulemaking	If Rulemaking Not Necessary, Explain
Ch. 2019-137, Laws of Florida, Effective July 1, 2019 (CS/CS/HB 23)(Use of telehealth services)	§§456.47; 627.42396; 641.31(45), F.S.	64B16-30.001, F.A.C. (Disciplinary Guidelines)	Not pursuant to this new statute	8/26/2019 Vol. 45/166, F.A.R.	December 2019	The statute is self-executing and does not require any mandated rulemaking. However, the Board will need to review the disciplinary guidelines to ensure that the board is in compliance with §456.079(1), F.S. (2019).

Ch. 2019-152, §2, Laws of Florida Effective July 1, 2019(CS/CS/CS HB 851)(Human Trafficking)	Created §456.0341, Fla. Stat.	N/A	No	N/A	N/A	This provision of the statute is self-executing and does not mandate rulemaking. Further, a failure to comply with Continuing Education provisions is addressed by the Department of Health upon attempted renewal of the license.
Ch. 2019-99, Laws of Florida, Effective July 1, 2019 (CS HB 19)(Prescription drug Importation program)	§§ 381.02035; 465.0157; 465.017(2); 499.005(20); 499.0051(12); 499.01; 499.012; 499.015(1); 499.065; 499.0285, F.S.	<u>64B16-33.001</u> , F.A.C. (International Export Pharmacy Permit)	Maybe*	7/26/2019 Vol. 45/165, F.A.R.	Unknown at this time due to Implementation of the International Prescription Drug Importation program	*Implementation of the International Export Pharmacy Permit is contingent upon Federal Approval of the International Prescription Drug Importation Program established in §499.0285, F.S. (2019). Therefore, mandatory rulemaking is contingent on Federal approval.

PART TWO
LAWS EXPECTED TO BE IMPLEMENTED THROUGH RULEMAKING

Part Two of this plan addresses those laws which the Board of Pharmacy intends to implement through rulemaking by July 1, 2020 that are otherwise not covered pursuant to Part One of this Plan. This Part does not include emergency rulemaking or any other rulemaking that may become necessary that was not evident to the Board at the time of the submission of this plan. Additionally, the listing of a law to be implemented does not mean the rule will necessarily be adopted or effective by July 1, 2020. §120.74(1)(b), Fla. Stat. (2019).

Rule Number And Title	Law Expected to Be Implemented Through Rulemaking	Intent of Rulemaking
<u>Chapter 64B16</u> , F.A.C. (Board of Pharmacy)	Multiple / Various Chapters 456 and 465, F.S.	Clarify, Simplify, and Increase Efficiency by Reviewing and updating all licensure application forms.
<u>64B16-26.302</u> , F.A.C. (Subject Matter for Consultant Pharmacist Licensure Renewal Continuing Education)	§465.0125, F.S.	Clarify, Simplify, and Reduce Regulatory Costs
<u>64B16-27.1001</u> , F.A.C. (Practice of Pharmacy)	§§465.003; 465.014; 465.026, F.S.	Clarify and Simplify, Increase Efficiency
<u>64B16-27.103</u> , F.A.C. (Oral Prescriptions and Copies)	§§465.003; 465.014; 465.022; 893.07, F.S.	Clarify, Simplify, and Increase Efficiency
<u>64B16-27.210</u> , F.A.C. (General Terms and Conditions to Be	§§465.022; 465.186, F.S.	Clarify and Reduce Regulatory Costs

Followed by a Pharmacist When Ordering and Dispensing Approved Medicinal Drug Products)		
<u>64B16-27.211</u> , F.A.C. (Prescription Refills)	§465.022, F.S.	Clarify and Increase Efficiency
<u>64B16-27.220</u> , F.A.C. (Medicinal Drugs Which May be Ordered by Pharmacists)	§465.186, F.S.	Clarify and Reduce Regulatory Costs
<u>64B16-27.4001</u> , F.A.C. (Delegation to and Supervision of Pharmacy Technicians; Responsibility of Supervising Pharmacist)	§465.014, F.S.	Clarify and Increase Efficiency
<u>64B16-27.410</u> F.A.C. (Registered Pharmacy Technician to Pharmacist Ratio)	§465.014, F.S.	Clarify and Increase Efficiency
<u>64B16-27.420</u> F.A.C. (Pharmacy Technician – Delegable and Non-Delegable Tasks)	§465.014, F.S.	Clarify and Increase Efficiency
<u>64B16-27.520</u> , F.A.C. (Positive Drug Formulary)	§465.025	Review to determine if the rule should be Repealed.

<p><u>64B16-27.530</u>, F.A.C. (Duty of Pharmacist to Inform Regarding Drug Substitutions)</p>	<p>§465.025, F.S.</p>	<p>Review to determine if the rule should be Repealed</p>
<p><u>64B16-27.700</u>, F.A.C. (Definition of Compounding)</p>	<p>§§465.003; 465.0155; 465.0265, F.S.</p>	<p>Clarify, Increase Efficiency and Review for needed updates.</p>
<p><u>64B16-27.797</u>, F.A.C. (The Standards of Practice for Compounding Sterile Products)</p>	<p>§§465.0155 and 465.022, F.S.</p>	<p>Clarify, Increase Efficiency, and Review for needed updates based on recent changes to USP chapters that are incorporated into the rule.</p>
<p><u>64B16-27.830</u>, F.A.C. (Standards of Practice – Drug Therapy Management)</p>	<p>§§465.003; 465.022; 465.0155, F.S.</p>	<p>Clarify and Reduce Regulatory Costs</p>

<u>64B16-27.831</u> , F.A.C. (Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education)	§§456.013; 456.42; 456.43; 465.0155; 465.003; 465.009; 465.016; 465.017; 465.022; 893.04, F.S.	Amend to delete unnecessary reference in subsection (5) (Electronic Prescribing) as it is now addressed by Ch. 2019-112, Laws of Fla.
<u>64B16-28.1191</u> , F.A.C. Unclaimed Prescriptions	§465.0255, F.S.	Reduce Regulatory Costs
<u>64B16-28.141</u> , F.A.C. (Requirements for use of an Automated Pharmacy System by a Community Pharmacy)	§§465.018; 465.022, F.S.	Clarify, Increase Efficiency and Reduce Regulatory Costs
<u>64B16-28.10801</u> , F.A.C. (All Permits – Delivery of Medicinal Drugs)	§465.022, F.S.	Clarify
<u>64B16-30.002</u> , F.A.C. (Minor Violations)	§456.073(3), F.S.	Increase Efficiency and Reduce Regulatory Costs
<u>64B16-30.003</u> , F.A.C. (Citations)	§456.077, F.S.	Increase Efficiency and Reduce Regulatory Costs

PART THREE
UPDATES TO PRIOR YEAR'S PLAN

Part Three of the Plan address whether there are any updates to the prior year's regulatory plan. §120.74(1)(c), Fla. Stat. (2019).

There are not any updates to the prior year's annual regulatory plan.

PART FOUR
CERTIFICATION PURSUANT TO §120.74(1)(d), Fla. Stat. (2019)

The undersigned hereby certify that they have reviewed this Annual Regulatory Plan and that the Board of Pharmacy regularly reviews all its rules to determine if the rules remain consistent with the Board's rulemaking authority and the laws being implemented, with the most comprehensive enhanced review having been completed on the 30th day of June 2015 with continuing board review through August 2019.

/S/ Jeffrey J. Mesaros

Electronic Signature
Jeffrey J. Mesaros, PharmD, J.D,
Chair of the Board of Pharmacy

September 9, 2019

Date Signed

/S/ D. D. Flynn, Esquire

Electronic Signature
David D. Flynn, Esquire
Senior Assistant Attorney General
Counsel to the Board of Pharmacy

September 9, 2019

Date Signed